REMARKS

Claims 1-16, 18,25,31,32,34 and 41-44 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. The Examiner contends that the claims contain subject matter which is not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

The Examiner on page 3 of the action sets forth a statement of the teachings of the prior art (item 2) which is respectfully submitted to be incorrect, for reasons that will be discussed later with respect to the prior art rejections.

Concerning item (4) on page 3 of the action, here again the statement by the Examiner is respectfully submitted to be incorrect and will be discussed in connection with the prior art rejections.

With respect to item (5) it is true that most of the claims permit the blockage of any microbe, since this is the invention. Blocking cell surfaces will be effective in preventing or minimizing the attachment thereto of microbes generally. In addition however, claim 44 is limited to bacteria. Moreover, the specification specifically refers to the treatment of bacterial infections (see page 10, line 4), yeast infections (page 10, lines 4 and 5), and viruses (common cold) (page 13, lines 6-8). See also the Examples, where gingival infections (Example 1), infectious diarrhea (Example 2), irritable bowel syndrome (Example 3), and bacterial vaginosis (Example 4) were effectively treated with isoleucine. Hence, the effectiveness of isoleucine for the treatment of various microbes has been fully disclosed in the specification.

With respect to item (6) on page 4 of the action, the Examiner questions how isoleucine can treat or prevent an entire group of microbes. The treatment or prevention

of an entire group of microbes results from the blockage of cell surfaces with isoleucine which minimizes or prevents the adhesion thereto by microbes (see e.g. page 5, lines 1-3).

Concerning the term "preventing" on page 5, line 8, this term does not imply a cure. First of all, the term "cure" refers to the bringing about of the recovery from a disease. The term "prevention" refers to keeping a disease from happening. Also, there is no provision in the specification suggesting or stating that the method of the invention provides a cure.

With respect to the Examiner's contention that "the specification provides no guidance on how the treatment or prevention of microbes can be provided through the use of one single amino acid, isoleucine", the Examiner's attention is respectfully directed to the extensive teachings in the specification. See e.g. pages 2-20.

Concerning item (7) on page 4 of the action, it is not understood what the Examiner means by the examples being too limited. If the Examiner is referring to a necessity for extensive clinical trials, such as those required for an NDA, there is no such requirement in patent law or practice.

The Examiner further contends that the examples are distinct from the scope of the claims. There is of course no requirement that the claims must be limited to the scope of the operating examples. Operating examples are in fact not even required in order to obtain claims to an invention.

Re item (8), the Examiner contends that "undue" and painstaking experimentation would be required to determine which particular microbes would be positively affected by isoleucine.

The microbial blocking quantities that can be used to obtain this effect are set forth in lines 16-19 on page 2. Any physician using isoleucine can readily determine the dosage quantity needed to obtain the above microbial blocking quantities. Moreover, as with all medications, titration of dosage to obtain an effective quantity for a particular patient and a particular condition is standard medical procedure.

In addition, on page 7, first paragraph, a readily implemented method for determining an effective dose of isoleucine is set forth in clear and easily understood language.

Furthermore, dosage forms for administration of isoleucine are set forth throught the specification; see e.g. pages 7-15, including the use of isoleucine as the only pharmacologically active component (page 8, line 19 and 20).

With respect to determining which particular microbes would be positively affected by the administration of isoleucine, this is readily and easily determined by using a disclosed dosage form to treat a patient having a particular microbial infection and titrating the dosage upward, if needed, until a positive effect is obtained. This is standard medical practice, employed by physicians even with well known marketed pharmaceuticals.

On page 5 of the action the Examiner contends that:

"The process steps and written description are insufficient and have not been presented in such a way as to allow one of ordinary skill in the art to understand and practice the invention. No specific formulations, specific amounts and specific procedures or administrations are set forth to allow one of ordinary skill to know how to

perform a method of block microbial adherence to eukaryotic cells by applying an isoleucine composition."

With respect to the inability of one of ordinary skill in the art to understand and practice the invention, the Examiner in item (3) on page 3 states: "The relative skill of those in the art is high". As discussed above, the specification and operating examples are replete with clear and extensive teachings leading to both an understanding of and practicing of the invention. Applicant fails to understand the Examiner's assertions to the contrary.

Concerning specific formulations, specific amounts and specific procedures, these are given throughout the description and operating examples. See pages 2 to 20, especially page 2 lines 16-19, and page7, line 1-7 and 8-15.

The methods of treatment of various conditions are set forth on pages 10-15, and in the operating examples on pages 15-20.

In view of the above discussion, withdrawal of the section 112 enablement rejection is respectfully requested.

On page 5, claims 1-6,8-16, 18,25, and 41-44 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Pedersen reference

The Examiner's interpretation of the claims as permitting mixtures of amino acids is respectfully submitted to be incorrect. Claim 1 for example limits the amino acid component to an isoleucine compound; hence excluding mixtures of amino acids. The Examiner's statement that isoleucine is "preferred" is also not correct. It is the isoleucine compound that blocks microbial adherence to cell surfaces and not other amino acids, i.e. the invention relates only to isoleucine as the active agent.

Also, as set forth in a previous response, and as noted by the Examiner, Pedersen's compositions require the use of chelates of a metal ion, in which it is the metal ion that reduces microbial growth potential. The metal chelate is described on page 13 (of my web site copy) as the "resulting molecule has two or three five-membered heterocyclic ring structures containing a metal ion attached by coordinate covalent bonds to two or more non-metals in the same molecule. Such chelates differ from traditional salts by having different physical and chemical properties such as e.g. the nature of the chemical bonds involved in forming the different chemical structures."

The two paragraphs following this quotation make it additionally clear that the chelate is not an amino acid salt.

Hence, the amino acids used to form the chelates are reaction products only and do not exist as such in the chelate. Isoleucine does not have "two or three five-membered heterocyclic ring structures".

Hence, it is respectfully contended that the chelate of Pedersen is chemically unrelated to isoleucine, and functions by an entirely different mechanism, i.e. metal ion toxicity to microbes.

Also, as noted by the Examiner, Pedersen does not teach Applicant's claimed ranges. The compounds used in the respective inventions are chemically quite dissimilar and hence their respective ranges are respectfully submitted to be irrelevant. Moreover, since both the products and mechanisms of action are unrelated, any test of discover "optimum or workable ranges" cannot apply here.

Claims 1-13. 18, 25, 31, 32, 34 and 41-44 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Zeng reference (U.S. 6,770,306B1).

The Examiner has interpreted the present claims as permitting mixtures of amino acids, and refers to isoleucine as a preferred amino acid. As discussed above, this assumption is not accurate, since the present inventors have found that isoleucine, and only isoleucine and its stereoisomers and active analogs, have the unexpected benefits of blocking eukaryotic cell surfaces to prevent or at least significantly decrease microbial attachment to such cell surfaces. Accordingly, independent claims 1, 11, 18 and 32 were amended in the response dated 03/14/2005 to limit the amino acid component to isoleucine and its analogs. Also, claim 1 component B) excludes other amino acids as an additional pharmacologically active substance.

Hence, the claims exclude mixtures of amino acids, which are always used by Zeng (see e.g. claim 1 where nine amino acids are present, claim 2 where eight amino acids are present, etc.).

Moreover, Zeng's compositions containing amino acid mixtures are used to treat vaginitis resulting from highly acidic vaginas, i.e. as neutralizing agents. This disclosure has nothing to do with a method for blocking microbial adherence to eukaryotic cell surfaces (claims 1-10 and 41-44). Zeng does not teach any method for blocking cell surfaces using an isoleucine compound and not other amino acids.

With respect to composition claims 11-16, 17, 25, 31, 32 and 34, as discussed above, claim 11 limits the amino acid component to isoleucine stereoisomers and active isoleucine analogs, and component B) does not include other amino acids. Moreover,

claims 16, 18, 31, 32, and 33 relate to toothpastes or gels or wound or skin ointments or creams, clearly not disclosed by Zeng.

With respect to the amounts of isoleucine, as noted by the Examiner, Zeng does not teach Applicant's ranges of microbial blocking quantities for cell surfaces using only isoleucine as recited in claims 2-4. The argument re finding suitable ranges is not relevant, since the use of amino acid mixtures as neutralizing agents has nothing to do with using only isoleucine for the blocking of cell surfaces to block microbial adherence.

In the "Response to Arguments" on pages 11 and 12, the Examiner contends that with respect to the section 112 rejection, the microbial blocking quantities are not recited in the generic claims. This is respectfully submitted to be irrelevant – the section 112, first paragraph rejection refers to the "written description of the invention", and is not limited to the claims. The written description is contended to be fully enabling.

The Examiner then argues that the instant process is not enabled to demonstrate how to measure and identify specific microbes. This argument is not understood since the microbiological identification of microbes results from cultures taken from an infected patient, as well as from specific symptoms readily recognized by the medical profession.

The Examiner again refers to the claims as not "limited to the specific scopes argued by the Applicant." As stated above, enablement under the first paragraph of section 112 refers to the "written description of the invention," and not to the scope of the claims.

Concerning the Pedersen reference on page 12 of the action, the Examiner contends that "the presence of metal ions is considered equivalent to Applicant's

invention". As discussed above, the metal chelates of Pedersen are cyclic compounds with which the present invention is not in any way related. The use of a mixture of amino acids by Pedersen to form his metal chelates are reactants, not present as such in the cyclic chelate compounds.

With respect to the arguments for the Zeng reference, the Examiner contends that "the mixtures function in a similar manner". This is not in fact correct. Zeng's mixtures of amino acids function as neutralizing agents for highly acidic vaginas, i.e. as reactants for removing acidic components from the vagina. This is not functioning in a similar manner to the use of a single amino acid, isoleucine, to block microbial adherence to cell surfaces. There is moreover no reason to assume that the resulting reaction products will leave sufficient unreacted isoleucine to function as effective blocking agents on cell surfaces, particularly since Zeng does not teach or suggest any reason for using quantities of neutralizing agents in excess of those needed to neutralize the acidic components in the highly acidic vaginas.

Concerning claim 11, this claim does not permit the presence of other amino acids in either component A) or component B).

In view of the above discussion, it is respectfully contended that (a) the claims are free from section 103 rejections over the prior art, and (b) that the specification is fully enabling under section 112.

Allowance of claims 1-16, 18, 25, 31, 32, 34 and 41-44 is respectfully requested.

Respectfully submitted,

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